

Notice of Allowability	Application No.	Applicant(s)	
	09/701,140	HAWTIN, BRIAN	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Appeal Brief filed on June 15, 2005.
2. ☒ The allowed claim(s) is/are 3, 5, 9, 11, 12, 28, 32, 33, which are renumbered to claims 3-8, 1, 2.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>10/2005</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Burns on September 30, 2005.

The application has been amended as follows:

In claim 32, after "skin condition", insert "selected from a group consisting of atopic dermatitis and eczema".

Cancel claim 17.

REASONS' FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Claims are allowed in view of i) the documents submitted under 37 C.F.R. 1.132, submitted on September 29, 2003, and September 24, 2005; and ii) the claim amendment to limit the scope of the specific skin conditions that are the subject matter of the clinical trials [^]the said documents.

The claimed invention is directed to a method for treating atopic dermatitis and eczema by topically applying a composition comprising an aqueous phase and an oil phase, about 1-5 % w/v of an amphoteric surfactant, about 0.4-4 % w/v of an alkoxylated cetyl alcohol, and about 1/10 % w/v of a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium.

Totten et al. (GB 2202145 A), was cited to show that it is well known in pharmaceutical art to treat atopic dermatitis by topically applying an oil-in-water composition comprising nedocromil sodium and surfactants such as glyceryl monostearate, cetostearyl alcohol. The reference also generally teaches using cetomacrogol ethers (ethoxylated cetyl alcohol), but fails to teach the amount or the concurrent use of the surfactant with an amphoteric surfactant as required by the present claims. Although Jacobs et al. (US 5939085) teach that amphoteric surfactants are used up to 20 % by weight in an oil-in-water emulsion to provide stability to the composition and skin smoothing property, the combined teachings of the reference do not render obvious the claimed method of using amphoteric surfactants in combination with ethoxylated cetyl alcohol in a specific amount to enhance the effectiveness of nedocromil sodium and sodium cromoglycate to treat atopic dermatitis and eczema as demonstrated by applicants.

The Rule 132 declaration filed on September 29, 2003 cites Van Bever et al., Eur. J. Pediatr. (1989) 149: 74 to show that a 4 % nedocromil sodium cream is found not effective in treating atopic dermatitis and eczema as compared to placebo. The Van Bever et al. article also states that nedocromil sodium "showed activity similar to that of sodium cromoglycate but is markedly more potent." The declarant indicates that the composition used in the Van Bever et al. article is made according to the Totten patent.

The data submitted on September 29, 2003, and the declaration filed on September 24, 2004 show that Altoderm formulation comprising 4 % w/w/ sodium

cromoglycate in an emulsion shows improved treatment of atopic dermatitis and eczema over placebo. The declarant states that Altoderm contains disodium cocoamphodiacetate and ethoxylated cetyl alcohol, which are used in the present invention. The results of the clinical trial also indicate that the patients on the Altoderm treatment started using corticosteroids less frequently, in favor of Altoderm. Thus, it is viewed that applicants have established sufficient evidence to show that the present formulation comprising amphoteric surfactants and ethoxylated cetyl alcohol in a specific amount provides unexpected results of improved delivery of the polar drugs, sodium cromoglycate and nedocromil sodium in the treatment of atopic dermatitis and/or eczema.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

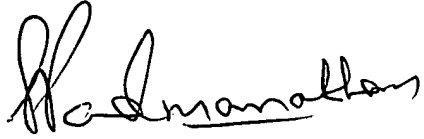
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER